DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-687/S-011

Danco Laboratories, LLC
Attention: (b)(6)
resident and Chief Executive Officer
P.O. Box 4816
New York, NY 10185

Dear (b)(6)

Please refer to your new drug application (NDA) submitted December 20, 2004, received December 21, 2004, under section 505(b) of the Federal Food, Drugs, and Cosmetics Act for MIFEPREX ® (mifepristone) Tablets.

This supplemental new drug application provides for the addition of a POST-MARKETING section of the label.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the labeling submitted on December 20, 2004.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-687/S-011." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call (b)(6)
(b)(6)

Sincerely,

{See appended electronic signature page}
(b)(6)

Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/
(b)(6)

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